

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

11 JHP PHARMACEUTICALS, LLC, a) Case No. CV 13-07460 DDP (JEMx)
12 Delaware limited liability)
13 company,) **ORDER GRANTING IN PART AND**
14 Plaintiff,) **DENYING IN PART DEFENDANTS'**
15 v.) **MOTIONS TO DISMISS**
16 HOSPIRA, INC., a Delaware)
17 corporation; INTERNATIONAL)
18 MEDICATION SYSTEMS, LTD., a)
19 Delaware corporation; and)
AMERICAN REGENT, INC., a New)
York corporation,)
Defendants.)

Presently before the court are two motions to dismiss the complaint brought by Par Sterile Products, LLC, against the Defendants American Regent, Inc., Hospira, Inc., and International Medical Systems, Ltd. The complaint alleges false or misleading advertising and labeling, based on the Lanham Act and equivalent state statutes. The Defendants' motions essentially argue that this Court, in deciding the case, would intrude on matters Congress has left exclusively to the discretion of the FDA. The Plaintiff,

1 on the other hand, argues that its complaint does not rest on
2 matters requiring the expertise and authority of the FDA to
3 resolve, and dismissal is not appropriate.

4 For reasons discussed below, the Court grants the motions in
5 part and denies them in part.

6 **I. BACKGROUND**

7 *A. Factual Background*¹

8 Par Sterile Products, LLC ("Par") is a manufacturer of
9 injectable epinephrine under the brand name ADRENALIN. Defendants
10 American Regent, Inc. ("American Regent"), Hospira, Inc.
11 ("Hospira"), and International Medical Systems, Ltd. ("IMS")
12 (collectively, "Defendants") are manufacturers of other injectable
13 epinephrine products.

14 In 2012, Par (then known as JHP Pharmaceuticals, LLC)
15 submitted a New Drug Application ("NDA") for its 1 mL and 30 mL
16 injectable epinephrine products to the U.S. Food and Drug
17 Administration ("FDA") under the brand name ADRENALIN. (Compl. ¶¶
18 3-4.) On December 7, 2012, the FDA, pursuant to its power under
19 the Food, Drug, and Cosmetic Act ("FDCA"), granted JHP approval to
20 market and sell the 1 mL version of ADRENALIN. (*Id.* ¶¶ 5-6.)² Par

22 ¹Both Par and Defendants Hospira and IMS have submitted to the
23 Court additional material in support of their positions.
24 "Generally, a district court may not consider any material beyond
the pleadings in ruling on a Rule 12(b)(6) motion." Hal Roach
25 Studios, Inc. v. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555
n.19 (9th Cir. 1989). Therefore, the Court declines to consider,
26 in ruling on these motions, either the Declaration of Harold
Storey, submitted by Par, or the Declaration of Jeffrey LeVee,
submitted by Hospira and IMS. This section draws exclusively from
27 the complaint for the facts alleged.

28 ²The NDA for the 30 mL ADRENALIN product was still pending at
the time JHP filed its complaint. (Compl. ¶ 4.)

1 alleges that it invested millions of dollars in complying with the
2 FDA approval process. (Id. ¶¶ 50-51.)

3 Par alleges that the Defendants all sell injectable
4 epinephrine products which are not FDA-approved (Compl. ¶¶ 55, 57),
5 an allegation which no Defendant denies. Par also alleges that the
6 Defendants mislead the public in four different ways.

7 First, Par alleges that the Defendants represent to consumers,
8 either overtly or through misdirection, that their products are
9 FDA-approved, when they are not. (Compl. ¶ 71.)

10 Second, Par alleges that the Defendants misleadingly advertise
11 their products as "safe" and "effective."³

12 Third, Par alleges that the Defendants advertise products that
13 are "illegal" to sell or market under the FDCA (Id. ¶¶ 56-57),
14 while representing to wholesalers and the public that they abide by
15 the law. Par thus alleges that the Defendants are misleading
16 wholesalers and the public as to the legality of their products.

17 Fourth, Par alleges that the Defendants omit from their
18 product labeling certain injection location and adverse reaction
19 information that Par's product *must* carry as part of its FDA-
20 approved labeling. This, Par contends, misleads the public into
21 thinking that Par's product is *more* dangerous than the generics,
22 because it can only be administered in certain locations and can
23 cause certain adverse reactions.

24

25

26 ³Throughout the complaint, Par's constant refrain is that the
27 Defendants market their products as "safe, effective, and
FDA-approved." (Compl. ¶ 71.) However, for reasons that will be
28 explained below, the Court finds it appropriate to separate the
safety/effectiveness issues from the question of FDA approval.

1 Par asserts a claim against the Defendants for each of these
 2 representations under the Lanham Act, 15 U.S.C. § 1125(a)(1), which
 3 forbids false or misleading advertising.⁴ Par also alleges actual
 4 injury, in the form of both competitive disadvantage and harm to
 5 reputation and goodwill.

6 Defendants counter that Par's Lanham Act claims should be
 7 dismissed, either because they are precluded altogether by the
 8 FDCA, because Par has failed to exhaust its administrative
 9 remedies, or because the FDA has primary jurisdiction over the
 10 claims and the case should be referred to the agency for a ruling.
 11 (Def. American Regent's Mot. Dismiss, § II; Defs. Hospira and IMS's
 12 Reply, § I; Def. American Regent's Reply, "Argument.") Defendants
 13 Hospira and IMS also raise the issue of the factual sufficiency of
 14 Par's claims. (Defs. Hospira and IMS's Mot. Dismiss, § I.C.2.)

15 *B. Procedural Background*

16 The initial complaint in this matter was filed on October 8,
 17 2013, and the Defendants filed motions to dismiss on November 27,
 18 2013. On February 3, 2014, Judge Michael Fitzgerald held a hearing
 19 on the motions. Ultimately, however, the Court ordered the motions
 20 denied without prejudice and the case stayed, pending the
 21 resolution of another Lanham Act/FDCA case in the Supreme Court,
 22 POM Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228 (2014).

23

24 ⁴Par also alleges violations of the California Business and
 25 Professions Code, §§ 17200 and 17500, which similarly prohibit
 26 misleading advertising. These state law claims, however, are not
 27 substantively addressed in the motions currently under
 28 consideration, however, as all Defendants agree that the state
 claims are "substantially congruent" to the Lanham Act claims.
 (Def. American Regent's Mot. Dismiss, § III.A.; Defs. Hospira and
 IMS's Mot. Dismiss, § II.) Par similarly focuses its arguments in
 opposition on the Lanham Act claims.

1 POM Wonderful was decided June 12, 2014. On June 19, 2014,
2 the Plaintiff in this case filed notice of the decision, and on
3 July 23, 2014, the Defendants filed new motions to dismiss, which
4 are the subject of this order.

5 **II. LEGAL STANDARD**

6 A complaint may be dismissed under Rule 12(b)(6) only if it
7 "either (1) lacks a cognizable legal theory or (2) fails to allege
8 sufficient facts to support a cognizable legal theory." Somers v.
9 Apple, Inc., 729 F.3d 953, 959 (9th Cir. 2013). "All allegations
10 of material fact in the complaint are taken as true and construed
11 in the light most favorable to the plaintiff." Williams v. Gerber
12 Products Co., 552 F.3d 934, 937 (9th Cir. 2008). "When there are
13 well-pleaded factual allegations, a court should assume their
14 veracity and then determine whether they plausibly give rise to an
15 entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679
16 (2009).

17 **III. DISCUSSION**

18 **A. Failure to Exhaust Administrative Remedies**

19 American Regent, alone among the Defendants, raises the issue
20 of failure to exhaust administrative remedies. It notes that under
21 21 C.F.R. § 10.45(b), citizens are required to submit a Citizen's
22 Petition to the FDA "before any legal action is filed in a court
23 complaining of the [agency's] action or failure to act." Were
24 Par's claim that the FDA had acted unlawfully, or that the FDA had
25 failed to act where it was required to do so, exhaustion would come
26 into play. Par makes no such claim, nor indeed any claim against
27 the FDA. Exhaustion of administrative remedies is not required, or
28 even possible, here.

1 *B. The Lanham Act, the FDCA, and the Scope of the POM Wonderful*
2 *Holding*

3 Because this action was stayed pending the outcome of the POM
4 Wonderful case in the Supreme Court, this Court begins its analysis
5 with the question of how, if at all, that decision has changed the
6 law of preclusion with regard to Lanham Act cases and the FDCA.

7 The Lanham Act broadly regulates representations made in the
8 course of commerce. It creates a cause of action against any
9 person who "uses in commerce any . . . false or misleading
10 description of fact, or false or misleading representation of fact,
11 which . . . misrepresents the nature, characteristics [or]
12 qualities . . . of his or her or another person's goods, services,
13 or commercial activities." 15 U.S.C. § 1125(a)(1). The purpose of
14 the Act is "to protect persons engaged in such commerce against
15 unfair competition" and "to prevent fraud and deception." 15 U.S.C.
16 § 1127.

17 The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-
18 399f, on the other hand, is intended "primarily to protect the
19 health and safety of the public at large." POM Wonderful, 134 S.
20 Ct. at 2234. Although the FDCA, too, regulates the labeling and
21 advertising of drugs, see 21 U.S.C. § 352, enforcement is not
22 through a private cause of action, but almost exclusively through
23 the actions of the FDA. Apart from a few situations in which
24 states may initiate enforcement actions, "all such proceedings for
25 the enforcement, or to restrain violations, of this chapter shall
26 be by and in the name of the United States." 21 U.S.C. § 337.

27 The Lanham Act and the FDCA are thus two discrete statutory
28 schemes that can regulate the advertising, marketing, and labeling

1 of food and drugs. Neither, however, precludes the other. In POM
 2 Wonderful, the Supreme Court held that "the FDCA and the Lanham Act
 3 complement each other" and that "Congress did not intend the FDCA
 4 to preclude Lanham Act suits" 134 S. Ct. at 2241. The
 5 Court noted that while "[e]nforcement of the FDCA and the detailed
 6 prescriptions of its implementing regulations is largely committed
 7 to the FDA," that agency "does not have the same perspective or
 8 expertise in assessing market dynamics that day-to-day competitors
 9 possess." Id. at 2238. Thus, the two statutes serve different
 10 functions and draw on different areas of expertise.

11 On the other hand, while articulating a broad vision of the
 12 statutes as compatible and complementary, the Court did, in
 13 passing, preserve the possibility that *some* Lanham Act suits might
 14 be precluded by the FDCA:

15 *Unlike other types of labels regulated by the FDA, such as*
 16 *drug labels, it would appear the FDA does not preapprove food*
 17 *and beverage labels under its regulations and instead relies*
 18 *on enforcement actions, warning letters, and other measures.*
 19 Id. at 2239 (citation omitted) (emphases added).

20 This passage suggests that, at a minimum, the Court might find
 21 a Lanham Act claim precluded by the FDCA where it turns on the
 22 content of a drug label, especially if that drug label were pre-
 23 approved by the FDA.

24 The Court further suggested, referencing Geier v. American
 25 Honda Motor Co., 529 U.S. 861 (2000), that a Lanham action might be
 26 barred where "the agency enacted a regulation deliberately allowing
 27 manufacturers to choose between different options," or where the
 28 Plaintiff's grounds for the Lanham Act claim otherwise conflict

1 with an affirmative policy judgment by the FDA. POM Wonderful, 134
2 S. Ct. at 2241.

3 There also exists a considerable body of circuit law, pre-POM
4 Wonderful, counseling restraint by courts in approaching Lanham
5 suits with regard to food and drug labeling and advertising. For
6 example, the Ninth Circuit held, in PhotoMedex, Inc. v. Irwin, 601
7 F.3d 919 (9th Cir. 2010), that "a private action brought under the
8 Lanham Act may not be pursued when, as here, the claim would
9 require litigation of the alleged underlying FDCA violation in a
10 circumstance where the FDA has not itself concluded that there was
11 such a violation."

12 PhotoMedex was the primary case relied on by the lower courts
13 in POM Wonderful, and although it was not specifically overruled,
14 its precedential value may be limited. But even PhotoMedex
15 recognized that the FDCA did not fully bar Lanham Act claims, where
16 the law was clear and did not require the FDA's expertise or
17 rulemaking authority to determine:

18 If, for example, it was clear that an affirmative statement of
19 approval by the FDA was required before a given product could
20 be marketed and that no such FDA approval had been granted, a
21 *Lanham Act claim could be pursued for injuries suffered by a*
22 *competitor as a result of a false assertion that approval had*
23 *been granted.*

24 PhotoMedex, 601 F.3d at 924-25 (emphasis added). And other
25 circuits have similarly concluded that where the issue of FDA
26 approval is straightforward, a Lanham action is viable. See
27 Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir.
28 2005) (surveying the precedent of multiple circuits and concluding

1 that Lanham Act claims "concerning representations of FDA approval"
 2 are viable unless they would require a "preemptive determination"
 3 of an issue within the FDA's exclusive authority).

4 Thus, although the extent of the shift in doctrine after POM
 5 Wonderful is not entirely clear, both the Supreme Court in that
 6 case and the Circuits in prior case law make clear two things.
 7 First, Lanham Act claims (even with regard to FDA approval) are
 8 not, as a general matter, precluded or barred by the FDCA. But
 9 second, *some* claims may require the expertise of the FDA to
 10 resolve.

11 Given the strong holding in favor of Lanham claims in POM
 12 Wonderful, all Defendants understandably seek to limit the reach of
 13 that decision, arguing that the case and its holding were about
 14 food labels *only* and did not reach the labeling, marketing, or
 15 advertising of drugs. The broad language of the opinion, however,
 16 does not support that view.

17 It is true that the Court makes frequent mention of "food and
 18 drink" or "food and beverage" in the course of its opinion, *e.g.*,
 19 POM Wonderful, 134 S. Ct. at 2334 ("The FDCA prohibits the
 20 misbranding of food and drink."); id. at 2237 ("[F]ood and beverage
 21 labels regulated by the FDCA are not, under the terms of either
 22 statute, off limits to Lanham Act claims."); id. at 2238 ("Although
 23 both statutes touch on food and beverage labeling"); etc.
 24 And, as noted above, the Court suggests a difference between food
 25 labeling, which is not subject to FDA pre-approval, and drug
 26 labeling, which is. Id. at 2239.

27 But the arguments, logic, and holding of *POM Wonderful* are
 28 couched in much broader language and strongly suggest a more wide-

1 ranging application. For example, the Court's argument that the
 2 Lanham Act draws on the market expertise of competitors, *id.* at
 3 2238, does not depend on anything peculiar to food and beverage
 4 labeling. Nor does its argument that "neither the Lanham Act nor
 5 the FDCA, in express terms, forbids or limits Lanham Act claims
 6 challenging labels that are regulated by the FDCA," *id.* at 2237;
 7 nor does its point that "the Lanham Act and the FDCA have coexisted
 8 since the passage of the Lanham Act in 1946" and Congress has never
 9 sought to address preclusion by one or the other. *Id.*

10 The logical building blocks of the Court's specific holding
 11 with regard to food and beverage labeling would seem to be equally
 12 applicable to food and beverage advertising, drug marketing,
 13 medical device labeling, cosmetics branding, or any other kind of
 14 marking or representation which would fall under both the Lanham
 15 Act and the FDCA, unless preclusion is required for some specific
 16 reason.⁵ The general presumption following POM Wonderful, then, is
 17 that Lanham Act claims with regard to FDCA-regulated products are
 18 permissible and, indeed, desirable. *Id.* at 2231 ("Allowing Lanham
 19 Act suits takes advantage of synergies among multiple methods of
 20 regulation.").

21 *C. Par's Lanham Act Claims*

22 Having established POM Wonderful's general presumption in
 23 favor of Lanham Act claims and against preclusion, the Court now
 24 turns to each of Par's bases for its claims.

25
 26 ⁵As noted above, the Supreme Court suggested two such reasons
 27 in POM Wonderful: the FDA may have pre-approved a particular
 28 labeling scheme, as in the labeling of FDA-approved drugs; or the
 agency may have authorized a menu of possible lawful choices for
 manufacturers, as was the case in Geier. (The common element, of
 course, is positive regulatory action in the matter by the FDA.)

1. FDA Approval

Par's fundamental argument with regard to FDA approval is that it is a sort of "Good Housekeeping Seal" for pharmaceuticals: it is the government's imprimatur on a product, indicating quality, safety, and desirability. Although some drugs may be lawfully sold without FDA approval, Part III.C.3 *infra*, if a product has been approved, consumers may take some assurance that it has been properly tested and meets the agency's minimum quality standards. This makes an FDA-approved product a more attractive product, whether at the wholesale, retail, or end user level. But it can also be expensive to get approval for a drug, so a company that chooses to invest in getting approval may operate at a competitive disadvantage if other companies can falsely represent to the public that their unapproved products are FDA-approved. Thus, representations that a drug is approved when it is not undermine the Lanham Act's public policy goals both by confusing consumers and by enabling unfair competition by producers who have not bothered to get FDA approval.

19 Par alleges that Defendants have misrepresented their products
20 as being FDA-approved in several ways. First, Par alleges that
21 Hospira advertises its product "as an NDA product . . . when, in
22 fact, Hospira has not obtained FDA approval of such an NDA."
23 (Compl. ¶ 70.) Second, Par alleges that Hospira, at least,
24 advertises that Par's ADRENALIN is the "brand name equivalent" of
25 its own product, and that it is a "generic" version of Par's
26 product.⁶ In a more general way Par alleges that Defendants

²⁸ "Par introduced these specific allegations against Hospira
(continued...)

1 encourage purchasers to think of their products as "comparable to
 2 or interchangeable with" Par's product. (*Id.* at ¶ 101.) Par
 3 contends that consumers will believe that Defendants' unapproved
 4 products are interchangeable with Par's approved one. Finally, Par
 5 alleges that Defendants advertise via certain industry lists, and
 6 that consumers expect the products on such lists to be "branded
 7 drugs or generic products," although Defendants' products are not
 8 "generics" as defined by the FDA. (*Id.* at ¶ 70.)

9 Defendants argue that claims based on such factual allegations
 10 are precluded, even post-POM Wonderful. Defendant American Regent
 11 cites to a recent case in the District of Utah, where the court
 12 found precluded a company's Lanham claim that a competitor was
 13 "falsely advertising that the current [medical device] model has
 14 FDA approval." Catheter Connections, Inc. v. Ivera Med. Corp., No.
 15 2:14-CV-70-TC, 2014 WL 3536573, *1, *6 (D. Utah July 17, 2014).
 16 But that case dealt with re-approval of new models of existing
 17 medical devices, a circumstance under which the FDA leaves it to
 18 the manufacturer, in the first instance, to determine whether it
 19 must apply for approval again or assume that the approval carries
 20 over. *Id.* at *5. Thus, the manufacturer there could plausibly
 21 claim that its product was, in fact, approved, at least until the
 22 FDA determined otherwise—a determination that would, of course, be
 23 entirely within the agency's purview. That is obviously very

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⁶(...continued)
 26 only at oral argument. Ordinarily, the Court would be reluctant to
 27 consider such late allegations as part of the complaint. However,
 28 because they sharpened the debate during oral argument, were
 adequately argued by Defendants, and were consistent with the
 other, more general allegations in the Complaint, the Court
 includes them in this discussion.

1 different from the present case, where the Defendants have never
2 had (and do not claim to have had) their products approved in the
3 first place.

4 In short, Par's claim is not precluded.

5 Defendants also argue that Par's claim falls under the
6 "primary jurisdiction" of the FDA. Under the primary jurisdiction
7 doctrine, a court, though having jurisdiction to hear the
8 complaint, may in some situations be required to "refer" the matter
9 to an administrative agency for resolution of a particular
10 technical issue. See Reiter v. Cooper, 507 U.S. 258, 268 (1993)
11 ("[C]laims properly cognizable in court [may] contain some issue
12 within the special competence of an administrative agency."). The
13 doctrine applies where there is "(1) the need to resolve an issue
14 that (2) has been placed by Congress within the jurisdiction of an
15 administrative body having regulatory authority (3) pursuant to a
16 statute that subjects an industry or activity to a comprehensive
17 regulatory scheme that (4) requires expertise or uniformity in
18 administration." United States v. Gen. Dynamics Corp., 828 F.2d
19 1356, 1362 (9th Cir. 1987).

20 There is no need to invoke primary jurisdiction doctrine as to
21 this claim. In this instance, it takes no special expertise to
22 determine whether the FDA has granted approval or not; nor are
23 there "uniformity of administration" concerns in the court making
24 that simple factual determination. The FDA itself maintains a
25 comprehensive list of approved drugs, see FDA, "Drugs@FDA,"
26 FDA.gov,
27 <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
28 (last visited Aug. 28, 2014), and while there may be cases where

1 approval is a gray area, no Defendant has argued that this is one.
2 Indeed, the fact that the Defendants' drugs are unapproved is not
3 contested by any party.

4 The same thing is true of the term "generic." To be declared
5 a "generic" drug by the FDA, a product must go through an approval
6 process prescribed by the agency. See "Generic Drugs: Questions
7 and Answers," FDA.gov (Sept. 3, 2013),
8 <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>. But the FDA maintains lists of approved generics,
9 just as it does for brand-name products. Id. If all that Par
10 alleges is that Defendants are advertising their products as
11 approved generics when they are not in fact approved, the Court
12 need not refer the question to the FDA's expertise to make factual
13 determinations.

14 Primary jurisdiction is not a bar to Plaintiff's claims here.

15 Defendants also allege that Par's complaint is factually
16 insufficient to support its Lanham claim. Defendants argue that
17 Par has not alleged specific statements by the Defendants
18 representing that their products are FDA-approved. Defendants then
19 cite primarily to Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th
20 Cir. 1993) for the proposition that a plaintiff cannot show that
21 the defendant implied FDA approval solely by introducing evidence
22 that the defendant put the product on the market.

23 With regard to Defendant Hospira, Par has, in fact, alleged a
24 specific representation: Par alleges that Hospira advertises its
25 product as "an NDA product." (Compl. ¶ 70.) While that is not
26 precisely the same as saying that the product is "FDA-approved," it
27 could easily be construed that way by the public, who should not

1 bear the burden of uncovering information that contradicts the
2 impression given by misleading advertising. See, e.g., Williams v.
3 Gerber Products Co., 552 F.3d 934, 939-40 (9th Cir. 2008) (holding
4 that the misleading labeling of a largely juice-free candy as
5 "fruit juice snacks" was not saved from a false advertising claim
6 by an FDA-approved ingredient list on the side of the box).
7 Therefore Par has made a plausible allegation that Hospira has made
8 misleading statements about its products' FDA approval status.

9 With regard to the other two defendants, however, it is not so
10 clear. Mylan, though not binding on this Court, makes a compelling
11 point: merely putting the product on the market is probably not a
12 representation that the product is FDA-approved. At the other end
13 of the factual spectrum, the Ninth Circuit has said that an actual
14 "false assertion" that the product was approved could sustain a
15 Lanham Act claim where "it was clear that . . . no such FDA
16 approval had been granted." PhotoMedex, 601 F.3d at 924-25.

17 Par's complaint falls somewhere between those two clear poles.
18 With regard to American Regent and IMS, at least, Par alleges no
19 overt "false assertion." On the other hand, Par's argument is more
20 subtle than that of the plaintiff in Mylan. Par does not merely
21 allege that putting the product on the market creates a misleading
22 impression that the drug is FDA-approved. Rather, it alleges that
23 the Defendants put their products on industry "Price Lists," and
24 that "buyers believe that all prescribed drugs identified on the
25 Price Lists are . . . FDA-approved." (Compl. ¶ 71.) And it
26 alleges that by listing their drugs as "generics," they are
27 implying that their products are "equivalents" of Par's FDA-

28

1 approved product, which might mislead consumers into thinking that
 2 Defendants' products are also FDA-approved. (*Id.* at 70.)

3 The problem, for Par, is that when the alleged representation
 4 is not an overt false statement, but merely misleading in context,
 5 the evidentiary showing required to sustain a Lanham claim is
 6 higher. In such a case, "proof that the advertising actually
 7 conveyed the implied message and thereby deceived a significant
 8 portion of the recipients becomes critical." William H. Morris Co.
v. Grp. W, Inc., 66 F.3d 255, 258 (9th Cir. 1995). Thus, to
 10 succeed on its claims against American Regent and IMS, Par must
 11 allege facts tending to show that the message "our product is FDA-
 12 approved" was actually conveyed to consumers by American Regent and
 13 IMS.

14 Here, Par does allege that consumers suffer actual confusion:
 15 "[B]uyers believe that all prescribed drugs identified on the price
 16 lists are . . . FDA-approved." (Compl. ¶ 71.) While Par has not
 17 yet produced actual evidence of these consumer beliefs, at the
 18 motion to dismiss stage, the Court can accept allegations of such
 19 facts as sufficient.

20 Par's Lanham Act claims that its competitors are falsely
 21 representing their products as having been FDA-approved are neither
 22 precluded by the FDCA nor within the primary jurisdiction of the
 23 FDA. Plaintiff's factual pleadings are sufficient to survive a
 24 motion to dismiss. As to the question of whether Defendants
 25 advertise their products as FDA-approved, the motion to dismiss is
 26 denied.

27 2. "Safe" and "Effective"

28

1 In its complaint, Par frequently alleges that the Defendants
 2 misleadingly represent their products as "safe, effective, and FDA-
 3 approved." (E.g., Compl. ¶ 72.) A determination of whether the
 4 Defendants' products are "safe" or "effective" might well fall
 5 within the primary jurisdiction of the FDA, or even be precluded
 6 entirely. However, the Court need not decide these issues today.
 7 Par alleges no facts to show that Defendants' products are either
 8 unsafe or ineffective. The repeated inclusion of such language may
 9 well be mere rhetorical excess on Par's part. However, to the
 10 extent that any of the Plaintiff's arguments about FDA approval
 11 rest on a determination of either safety or effectiveness, such
 12 arguments suffer a fatal lack of factual sufficiency. Thus, the
 13 sole question with respect to the surviving claim against
 14 Defendants is whether it overtly represents its products as being
 15 "FDA-approved," and *not* any question of safety or effectiveness.

16 3. Legality of the Defendants' Products

17 Par further alleges that the Defendants are falsely
 18 representing to consumers that their products "comply with all
 19 applicable laws, including the FDCA."⁷ (Compl. ¶¶ 60, 87.) And at
 20 least respecting Defendants Hospira and IMS, the complaint alleges
 21 sufficient facts to support a finding of overt statements to this
 22 effect. For example, Hospira is alleged to claim on its website
 23

24

25 ⁷In its Opposition, Par seems to suggest that no finding of
 26 illegality is needed: "Par's complaint is not based on a violation
 27 of the FDCA; it is based on Defendants' deceptive advertising of
 28 their products as equivalent to Par's." (Opp'n § I.B.) However,
 because the complaint raises allegations that the Defendants are
 misleading consumers by claiming to comply with the law, the Court,
 to resolve that claim, would have to make a factual finding with
 regard to the alleged FDCA violations.

1 that its complies with "applicable laws and other requirements."
 2 (Compl. ¶ 62.)

3 However, unlike a mere determination that a drug is or is
 4 not FDA-approved, the allegation that the drugs are being sold
 5 unlawfully is an issue that would require a more complex finding
 6 from the agency. Of course, if there were a clear and absolute
 7 rule making it patently unlawful to market any drug without going
 8 through the FDA approval process, it might not be necessary for the
 9 FDA to make a specific finding regarding the Defendants' products
 10 for the court to be able to determine that Defendants' products do
 11 not comply with the FDCA. PhotoMedex, 601 F.3d at 924-25.

12 And at first blush, 21 U.S.C. § 355(a) would seem to provide
 13 such a clear rule: "No person shall introduce or deliver for
 14 introduction into interstate commerce any new drug, unless an
 15 approval of an application filed pursuant to subsection (b) or (j)
 16 of this section is effective with respect to such drug." As even
 17 Par admits (Opp'n, "Factual Background"), however, there are some
 18 exceptions to this seemingly clear rule. Specifically, not all
 19 drugs marketed are "new," and many older drugs, even when updated,
 20 are exempt from the strictures of § 355(a). See 21 U.S.C. §
 21 321(p) (setting out grandfathered exceptions to the definition of
 22 "new drug"); see also FDA, Compliance Policy Guide Sec. 440.100
 23 Marketed New Drugs Without Approved NDAs and ANDAs, FDA.gov (Sep.
 24 16 2011), available at
 25 <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguide/manualsucm074382.htm> (discussing grandfather clauses in the
 26 FDCA and a "Prescription Drug Wrap-Up" program that brought many,
 27 but not all, old drugs into the fold of FDA approval).

1 In short, unlike the binary factual determination of whether
2 Defendants' products are, in fact, FDA-approved, the question of
3 legality directly implicates the FDA's rulemaking authority. The
4 determination of whether a drug is "new," and whether it can be
5 lawfully marketed under the FDCA, involves complex issues of
6 history, public safety, and administrative priorities that Congress
7 has delegated exclusively to the FDA.

8 That does not mean, however, that an allegation of illegality
9 under the FDCA could never form the basis of a successful Lanham
10 Act claim. As PhotoMedex and POM Wonderful both make abundantly
11 clear, where the court is not called upon to make determinations
12 within the exclusive purview of FDA authority, a Lanham Act claim
13 may be heard, even if the subject of the claim touches the area of
14 authority of the FDCA. Thus, this claim is not precluded as a
15 categorical matter. If the Plaintiff were to pursue the matter with
16 the FDA through its administrative procedures and obtain a clear
17 statement from the agency that the Defendants are selling their
18 products illegally or otherwise breaking the law, and if the
19 Defendants at that point chose to affirmatively declare in their
20 advertising that their products comply with the law, a federal
21 court could hear a Lanham Act claim for false advertising.

22 But this Court cannot proceed on this claim without a clear
23 statement by the FDA. To do so would be to arrogate the authority
24 of the FDA to decide, at least in the first instance, the legality
25 or illegality of marketing a particular substance. "It is clear to
26 us that FDA has power to determine whether particular drugs require
27 an approved NDA in order to be sold to the public. FDA is indeed
28 the administrative agency selected by Congress to administer the

1 Act, and [it] cannot administer the Act intelligently and
 2 rationally unless it has authority to determine what drugs are 'new
 3 drugs' . . . and whether they are [grandfathered]." Weinberger v.
 4 Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 624 (1973).

5 In short, in order to resolve Par's Lanham Act claim based a
 6 factual allegation that the Defendants are falsely claiming to
 7 comply with the law while in fact selling illegal products, the
 8 Court must resolve an issue that Congress has placed "within the
 9 jurisdiction of an administrative body having regulatory
 10 authority," under a comprehensive regulatory scheme. Gen. Dynamics
 11 Corp., 828 F.2d at 1362. And, crucially, this is not a question
 12 that can be resolved without expertise. Id. Moreover, Congress's
 13 decision to centralize authority to determine the legality of drug
 14 sales in the FDA was obviously intended to provide "uniformity of
 15 administration." Id. Thus, it seems clear that Par's Lanham Act
 16 claim with regard to legality requires a determination that is
 17 within the primary jurisdiction of the FDA.

18 4. Misleading Labeling

19 Finally, Par argues that the Defendants mislead the public by
 20 not including, in their packaging and labeling, all of the caveats
 21 and warnings that Par's product must carry under the terms of its
 22 FDA approval. This, it is alleged, creates the impression that
 23 Par's product is *less safe*, because it comes with *more* warnings
 24 than the Defendants' unapproved products.

25 Even if this allegation is true, Par faces several hurdles to
 26 basing a Lanham Act claim on it. First, because the deceit alleged
 27 is by implication rather than an overt false statement (such as
 28 "Par's ADRENALIN is less safe than our product!"), Par has the

1 burden of pleading at least some facts tending to show that the
2 alleged implied message is actually transmitted to the consumer.
3 William H. Morris, 66 F.3d at 258. Here the pleading is thin at
4 best. Par does not allege facts tending to show that the negative
5 message about its product is actually conveyed to consumers.
6 Indeed, the message is at least ambiguous: a savvy consumer of
7 pharmaceuticals, used to many pages of dire warnings, might well be
8 put on guard by the lack of similar warnings on the Defendants'
9 products.

10 Even if Par's pleading were sufficient to show that the
11 alleged implied message is actually transmitted to consumers,
12 however, the area of drug labeling was specifically singled out by
13 the POM Wonderful Court as being one where the FDA takes a
14 particularly active role. POM Wonderful suggested, at least
15 obliquely, that drug labeling might be an area where Lanham Act
16 claims are precluded.

17 Par argues that because the Defendants' products are
18 unapproved, they are effectively unregulated by the FDA. (Opp'n §
19 I.C.) There is, perhaps, some merit to this argument. Unlike the
20 situation envisioned in POM Wonderful, where the FDA would have
21 pre-approved a drug label, here Par correctly points out that the
22 FDA has taken no action at all with regard to these labels. Thus,
23 this case might not fall within POM Wonderful's caveat-in-dictum.

24 However, the Court need not resolve this thorny issue, because
25 there is a third, truly fatal problem with Par's allegation:
26 namely, it requires the Court to determine, as a matter of fact,
27 that Par's ADRENALIN is *not* less safe than the Defendants' various
28 products. After all, if ADRENALIN were less safe, the implied

1 message would not be false or misleading; it would be correct. Par
2 may find it obvious that its product is not less safe than the
3 Defendants' products, but it has not alleged any particular facts
4 tending to prove the comparative safety of the various products
5 involved.⁸

6 Because the Plaintiff's Lanham Act claim based on false or
7 misleading labeling requires a showing of facts not properly
8 pleaded, this claim is dismissed as to all Defendants.

9 **IV. CONCLUSION**

10 For all the reasons discussed above, Plaintiff's Lanham Act
11 claim and corresponding state law claims based on false
12 representations of FDA approval survive, and the Defendants'
13 motions are denied.

14 Plaintiff's claims based on false or misleading
15 representations that the Defendants's products comply with the law
16 are dismissed without prejudice, so that the Plaintiff can, if it
17 wishes, file a petition with the FDA to have its competitors'
18 products declared unlawful.

19 Finally, any claims based on representations that the
20 Defendants' products are "safe" and/or "effective" are dismissed.
21 Claims that the Defendants' labels and packaging are misleading

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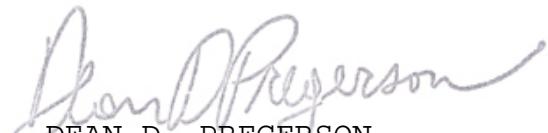
27 ⁸Even if Par had alleged such facts, however, the safety
28 determination would almost certainly require the scientific
expertise of the FDA, and so would likely fall within the agency's
primary jurisdiction.

1 because they imply that their products are safer than Plaintiff's
2 are also dismissed.

3 The motions to dismiss are thus granted in part and denied in
4 part.

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6 IT IS SO ORDERED.

7 Dated: October 7, 2014


DEAN D. PREGERSON
United States District Judge

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